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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,405	01/06/2004	Jerome B. Riebman	BIG-101	3191
39013	7590	09/07/2005	EXAMINER	
MOAZZAM LATIMER LLP 1474 NORTH POINT VILLAGE CENTER #320 RESTON, VA 20194-1190			ALTER, ALYSSA M	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/751,405	Applicant(s) RIEBMAN ET AL.	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 5 and 16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory.

The examiner recommends changing the following:

As to claim 5, "that attaches the tip to" to --adapted to attach the tip to--.

As to claim 16, "locking that locks the" to --locking that is adapted to lock the--.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 11, 22 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11, 22 and 32 include an improper Markush group.

A Markush group, recites members as being "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). *Ex parte Markush* sanctions claiming a genus expressed as a group consisting of certain specified materials.

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The examiner recommends changing the claim language from "wherein the source of blood is any one of" to --wherein the source of blood is selected from a group consisting of--.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5, 9-16, 20-25, 27 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Normann (US 3,974,825). Normann discloses a remote electrical monitoring of gas activated blood pumps that are employed outside or inside the body of a human.

As to claims 1-2, 9, 12-14, 20 and 23-24, Figure 1 depicts the blood chamber 20, the fluid chamber 30, flexible membrane 18, fluid conduit 34, blood port 24 and blood conduit 16. The examiner considers the opening in the fluid chamber 30, where the fluid chamber is connected with the fluid conduit 34, to be the fluid port.

As to claims 3, 5, 16, 25 and 27, since the pump can be used as a left ventricular bypass of the human heart, the blood inlet 14 and the blood outlet 16 are thus connected to the vasculature through some type of attachment means. The examiner considers the end of the inlet and end of the outlet to terminate into a tip portion, which is then attached to the vasculature.

As to claims 4, 10, 15 and 21, the functional language and introductory statement of intended use of claims 4 and 15 has been carefully considered but is not considered to impart any further structural limitations over the prior art. Since Normann utilizes a

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blood pump as claimed by the Applicant, Normann is therefore capable of being used in the vasculature. In addition nothing prevents Normann from attaching the blood pump to the vasculature through a means other than suture anastomosis. Therefore, the blood pump is capable of being attached by a means other than suture anastomosis. The functional language and introductory statement of intended use of claims 10 and 21 has been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Normann utilizes a blood pump as claimed by the Applicant, Normann is therefore capable of being used in conjunction with the heart in the mediastinal space. In addition nothing prevents Normann from being implanted in the mediastinal space. Therefore, the blood pump is capable of being implanted in the mediastinal space.

As to claims 10, 21 and 31, the mediastinal space or the mediastinum, according to MedTerms Medical Dictionary, is "the area between the lungs. The organs in this area include the heart and its large veins and arteries, the trachea, the esophagus, the bronchi, and lymph nodes". Therefore, since the blood pump is used with the heart, it is located in the mediastinal space.

As to claims 11, 22 and 32, since all of the blood passes through the heart, any blood pump uses the heart as a source for blood.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 6-8, 17-19, 26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Normann (US 3,974,825). Normann is silent about the attachment means of the blood pump to the vasculature. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the attachment as taught by Normann with an attachment without the use of suture anastomosis, since it is known in the art that there are other means of attachment besides sutures. Such as a shunt or encasement means, like a mesh jacket.

As to claims 6-8, 17-19 and 28-30, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the maximum volume of the blood chamber, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05).

2. Claims 6-8, 17-19 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Normann (US 3,974,825) in view of Giambruno (US 6,669,726). Normann discloses the claimed invention except for the maximum volume of the blood chamber. Giambruno teaches that it is known to have blood chambers with a capacity between 20mL to 120mL as set forth in column 14, lines 1-3, for the purpose of modifying an artificial heart. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the blood chamber as

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taught by Normann with the blood chamber capacity range as taught by Giambruno, in order to modify the blood pump to meet specific patient's needs.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Goldschmied (US 3,568,214) discloses an artificial heart system and method of pumping blood by electromagnetically pulsed fluid.
2. Wurzel (US 4,781,715) discloses a cardiac prosthesis having integral blood pressure sensor.
3. Palmer (US 6,579,223) discloses a blood pump.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alyssa M Alter
Examiner
Art Unit 3762



JEFFREY R. JASTRZAB
PRIMARY EXAMINER
9/6/05